K 101333

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510(K) SUMMARY

Prepared – December 12, 2004

JUN 14 2010

TRADE NAME	Cryocare CS Surgical System
COMMON NAME	Cryosurgical unit and accessories
CLASSIFICATION	Class II (21 CFR 878.4350)
SUBMITTED BY	Endocare, Inc. as wholly own subsidiary of Healthtronics, Inc. 9825 Spectrum Drive Building 2 Austin, TX 78717 Contact: Cheryl Blake 949-285-3517 e-mail: cherylblake@cox.net
PREDICATE DEVICE	K060279 - Endocare Cryocare CS Surgical System Decision date: February 26, 2006
DEVICE DESCRIPTION	The CRYOcare V-probe is a CRYOprobe accessory to be used in conjunction with the CRYOcare CS Surgical System. The indications for use have not changed. The V-Probe delivers cold temperatures via Argon gas utilizing the Joules Thompson principle to targeted tissue. The patient contact V-Probe (an accessory item to the CRYOcare CRYOsurgical CS System) is supplied as a single use Sterile Disposable item.

INDICATIONS FOR USE

The CRYOcare CS Surgical System has the **same intended use** as previously cleared for the Cryocare CS Surgical System – K060279 Decision Date February 28, 2006.

The Cryocare CS Surgical system has the same intended use as previously cleared. The CRYOsurgical CS Surgical System and accessories is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

In addition the system is intended for use in the following indications:

- General surgery

  Destruction of warts or lesions

  Palliation of tumors of the oral cavity, rectum and skin

  Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions.

- Urology

  Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia

- Gynecology

  Ablation of malignant neoplasia or benign dysplasia of the female genitalia

- Oncology

  Ablation of cancerous or malignant tissue

  Ablation of benign tumors

  Palliative intervention

	• Dermatology Ablation or freezing of skin cancers and other cutaneous disorders • Proctology Ablation of benign or malignant growths of the anus or rectum Ablation of hemorrhoids • Thoracic surgery Ablation of arrhythmic cardiac tissue Ablation of cancerous lesions
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The Cryocare CS Surgical System has the following similarities to that of the previously cleared predicate devices: • Has the same intended use; • The 10LAP4 ultrasound probe is the same as Teratech's cleared under K043278and is intended for the same clinical application; • Uses the same operating principle and has not altered the fundamental technology; • Incorporates the same system design; • Incorporates the same patient contacting materials; • Same manufacturing materials; and • Packaged and sterilized using the same materials and processes. In summary, the modified Cryocare CS Surgical System described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 14 2010

Endocare, Inc.
% Underwriters Laboratories, Inc.
Mr. Ned Devine
Senior Staff Engineer
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K101333
Trade/Device Name: Cryocare CS Surgical System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cyrosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: May 29, 2010
Received: June 02, 2010

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K101333

Device Name: **Cryocare CS Surgical System**

Indications for Use:
The Cryocare CS Surgical System is intended for use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts.

In addition, the system is intended for use in the following indications:

General Surgery

- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ (Per 21 CFR 801.109)

for mpm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101333

Indications for Use Statement (Continued)

Urology

- Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Neurology

- Freezing of nerve tissue in pain management/cryoanalgesia

Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders

Proctology

- Ablation of benign or malignant growths of the anus or rectum
- Ablation of hemorrhoids

Thoracic Surgery

- Ablation of arrhythmic cardiac tissue
- Ablation of cancerous lesions

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number_____ Prescription Use __X__ (Per 21 CFR 801.109)

PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT
(as required by 21 CFR 807.87(k))